

Doc Code: AP.PRE.REQ

PTO/SB/33 (07-09)

Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)	
		4532660/55140	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on _____ Signature _____ Typed or printed name _____	Application Number	Filed	
	10/532,775	10/07/2005	
	First Named Inventor Masayoshi Yamaguchi		
	Art Unit	Examiner	
	1614	Raymond J. Henley, III	
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.			
This request is being filed with a notice of appeal.			
The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.			
I am the		/kentaherink/	
<input type="checkbox"/> applicant/inventor.		Signature	
<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)		Kent A. Herink	
		Typed or printed name	
<input checked="" type="checkbox"/> attorney or agent of record.	31025	515-288-2500	
Registration number		Telephone number	
<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34.		August 17, 2010	
Registration number if acting under 37 CFR 1.34		Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.			
<input checked="" type="checkbox"/> *Total of 1 forms are submitted.			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)	
)	Group Art Unit 1614
Masayoshi Yamaguchi)	
)	
Serial No. 10/532,775)	Examiner: Raymond J. Henley, III
Filed: October 7, 2005)	
For: Osteogenesis Promoter Containing)	
Beta-Cryptoxanthin as the Active)	
Ingredient)	

STATEMENT IN SUPPORT OF PRE-APPEAL REQUEST FORM

Independent claim 19 recites:

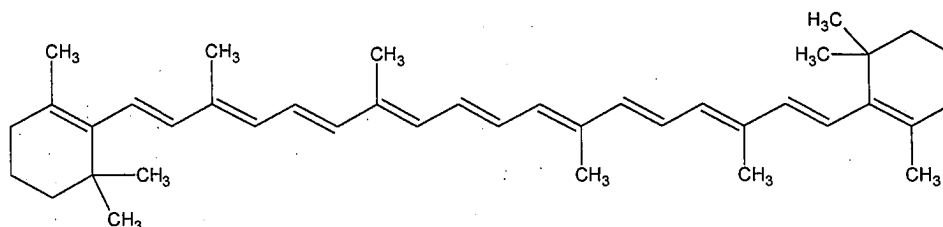
19. A method of ameliorating bone loss problems associated with aging in a person in need thereof, comprising administering to the person in need thereof an amount of purified **β-cryptoxanthin** effective to ameliorate the bone loss problems associated with aging. (Emphasis added.)

All of the claims recite methods utilizing β-cryptoxanthin.

In the Office Action mailed May 17, 2010, claims 19, 21, 22, 24, 25 and 27 are rejected under 35 U.S.C. Section 102(b) as being anticipated by Shlyankevich (U.S. Patent No. 5,424,331). The Patent Office states (page 3):

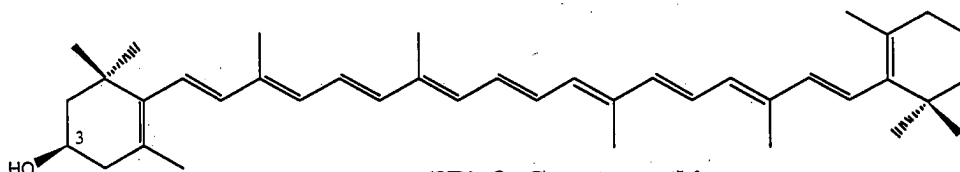
“Shlyankevich teaches a method for treating osteoporosis, (a.k.a. a diseased of decreased osteogenesis), which comprises administering to a patient in need thereof an effective amount of **beta-carotene, (a.k.a. beta-cryptoxanthin)** which may be in amounts of 6 mg or 20 mg (see the abstract, col 4, lines 24-31; and Examples 1 and 3).” (Emphasis added.)

The Patent Office has made a clear error. Beta-carotene and beta-cryptoxanthin are distinct compounds with distinct properties; beta-carotene is not “also known as” beta-cryptoxanthin. Beta-carotene has the molecular formula $C_{40}H_{56}$, a molecular weight of 536.88 and a CAS Registry No. of 7235-40-7. The structure of beta-carotene is below:



B-Carotene

Beta-cryptoxanthin has the molecular formula $C_{40}H_{56}O$, a molecular weight of 552.88 and a CAS Registry No. of 472-70-8. The structure of beta-cryptoxanthin is below:



(3R)-β-Cryptoxanthin

Beta-carotene is a carotenoid that is a precursor of Vitamin A, sometimes referred to as a pro-Vitamin A. Vitamin A has been shown to increase the risk of fractures among women (Claire-Juvera, et al., Vitamin A and Retinol intakes and the risk of fractures among participants of the Women’s Health Initiative Observational Study, *Am J Clin Nutr* 2009; 89:323-30). Beta-cryptoxanthin is an oxygenated carotenoid, i.e., a xanthophyll, and not a carotene. The presence of the oxygen moiety changes the polarity of the molecule and its biological properties.

It is well known in the art that these are distinct molecules with distinct biological properties. A reference which teaches properties or uses of beta-carotene cannot anticipate the properties or uses of beta-cryptoxanthin. For this reason, it is respectfully requested that the Office Action mailed May 17, 2010, be withdrawn and the application passed to allowance.

Respectfully submitted,

Date: August 17, 2010

/kentaHerink/

Kent A. Herink

Registration No. 31025

DAVIS, BROWN, KOEHN,

SHORS & ROBERTS, P.C.

215 10th Street, Suite 1300

Des Moines, Iowa 50309

Telephone: (515) 288-2500

ATTORNEYS FOR APPLICANT